

Remarks

I. The Restriction Requirement

The Examiner has restricted the originally filed claims into the following groups:

- I.** Claims 1-9, 12, 14-22 and 25, drawn to isolated nucleic acids that encode ET2 or GABRE polypeptides, vectors and host cells comprising such, as well as methods of producing the polypeptide, classified in Class 435, subclass 96.1.
- II.** Claims 10, 13, 23 and 26, drawn to purified ET2 or GABRE polypeptides, classified in Class 530, subclass 350.
- III.** Claims 11 and 24, drawn to antibodies to ET2 or GABRE polypeptides, classified in Class 530, subclass 387.1.

Applicants respectfully traverse the restriction requirement as it applies to Groups I and II. It is the Examiner's position that nucleic acid molecules and the encoded protein are patentably distinct because the nucleic acids encompassed by the claims of Group I are physically and functionally distinct from the polypeptides of Group II. (Office Action, page 2.) The Examiner further assert that, due to the separate status in the art of the subject matter categorized into each group, the search and examination of both of these groups together would constitute an undue burden. (Office Action, page 3.)

As noted by the Examiner, even where two patentably distinct inventions appear in a single application, restriction remains improper unless the examiner can show that the search and examination of both groups would entail a "serious burden." (*See* MPEP § 803.) Applicants point out, however, that the Examiner has clearly failed to make such a showing in the present instance.

Applicants submit that a search of the nucleic acid claims of Group I would clearly provide useful information for the polypeptide claims of Group II. This is because the genetic

code is known. Moreover, in many if not most publications, where a published nucleotide sequence is an open reading frame, the authors also include, as a matter of routine, the deduced amino acid sequence. Thus, the searches for nucleic acid molecules and polypeptides encoded by these molecules would clearly be overlapping.

Accordingly, Applicants request that the Examiner reconsider and withdraw the restriction requirement as applied to Groups I and II.

II. The Amendments to the Specification

The specification has been amended to correct an error in the form of the biological materials deposited as American Type Culture Collection (ATCC) Deposit No. 209642. Specifically, the specification states that a cDNA clone encoding the GABRE polypeptide was deposited in host cells. However, as evidenced by the attached ATCC deposit receipt, this cDNA was deposited as plasmid DNA. The amendment to page 14, line 5, of the specification, thus, changes the reference to material deposited with the ATCC from "deposited host" to "deposited plasmid." This amendment does not introduce new matter.

Page 18, lines 22-23, of the specification has been amended to correct an obvious typographical error in the amount of ingredients listed for 5x SSC (sodium chloride/sodium citrate). An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of the error in the specification, but also the appropriate correction. (M.P.E.P. § 2163.07.) Here, the recognition of the typographical error, along with the correction of the error, in the amount of the ingredients listed for 5x SSC, is obvious to one skilled in the art, and, therefore, the correction does not constitute new matter.

5x SSC is a well known solution used in hybridization solutions. (*See, e.g.,* Exhibit A, CURRENT PROTOCOLS IN MOLECULAR BIOLOGY, John Wiley and Sons, N.Y., Supplement 35, page 2.10.7 (1996).) SSC is normally made as a 20x stock solution, and then

diluted accordingly for a particular use. Exhibit B shows that a 20x SSC stock solution contains 3M NaCl and 0.3M trisodium citrate. (Exhibit B, CURRENT PROTOCOLS, page A.2.5.) To make a 5x SSC solution, the 20x SSC solution must be diluted by one-fourth. Therefore, a 5x SSC solution contains 750mM NaCl ($3\text{M} \div 4 = 750\text{mM}$) and 75mM trisodium citrate ($0.3\text{M} \div 4 = 75\text{mM}$).

One skilled in the art would have immediately recognized that the amount of ingredients listed in the specification for a 5x SSC solution was incorrect. Rather than describing a 5x SSC solution, made up of 750mM NaCl and 75mM trisodium citrate, the specification inaccurately listed the ingredients for a 1x SSC solution. Further, the skilled artisan, in recognizing the typographical error, could easily have adjusted the amount of ingredients described in the specification to properly make a 5x SSC solution. Therefore, the correction of this typographical error does not introduce new matter.

Page 18, line 24, of the specification has also been amended to correct an obvious typographical error in the amount of denatured, sheared salmon sperm DNA in the hybridization solution used in an example of "stringent hybridization conditions". The originally filed specification refers to the inclusion of 20 g/ml denatured, sheared salmon sperm DNA but should recite 20 $\mu\text{g/ml}$.

The inclusion of agents such as salmon sperm DNA as blocking agents is well known in the art. (See, e.g., Exhibit A, CURRENT PROTOCOLS, page 2.10.7.) One skilled in the art would know that salmon sperm DNA is present in hybridization solutions in $\mu\text{g/ml}$ quantities and thus would immediately recognize the above-described typographical error in the specification. See *id.* Further, the skilled artisan, in recognizing the typographical error, could easily have adjusted the amount of ingredients described in the specification to properly included 20 $\mu\text{g/ml}$ denatured, sheared salmon sperm DNA in the hybridization solution. Therefore, the correction of this typographical error does not introduce new matter.

Conclusion

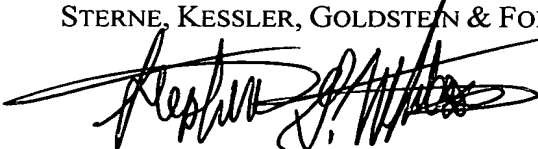
Applicants request that the Examiner reconsideration and withdrawal the restriction requirement as it applies to the claims of Groups I and II. Applicants also request entry of the amendments to the specification set out above. None of these amendments introduce new matter.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 19-0036.

It is respectfully believed that this application is now in condition for substantive examination. Early notice to this effect is respectfully requested.

Respectfully submitted,

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